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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,130	05/19/2006	Karin A. Eidne	21004-002US1	9404
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FISH & RICHARDSON P.C.			SNYDER, STUART	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/580,130	Applicant(s) EIDNE ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,7-20 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,7-20 and 22-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Cancellation of claims 1-2, 4-6 and 21 and amendment of claims 7-8, 9, 15, 19, 13, 18-19 and 23 in the filing of 8/25/2008 is acknowledged.

Election/Restrictions

2. Applicant's election with traverse of Group III, claims 3, 20 and 22 in the reply filed on 8/25/2008 is acknowledged. The traversal is on the ground(s) that the cited reference does not teach sequential FRET transfer amongst 3 components. This is not found persuasive because it is well known in the art that the emission spectra of fluorescein overlaps with the absorption spectra of both ROX and TMR, that the emission spectra for TMR overlaps with the absorption spectra of ROX, and therefore sequential FRET transfer of FAM to TMR to ROX will happen when the three fluorophores are within close physical proximity to each other. The requirement is still deemed proper and is therefore made FINAL.
3. The Examiner has determined that amendment of claims 7-8, 9, 15, 19, 13, 18-19 and 23 to depend on claim 3 places the claims and dependent claims into the one inventive group. Thus, all pending claims now fall within group III of the previous restriction scheme and are examined herein.

Specification

4. The disclosure is objected to because of the following informalities: The Brief Description of the Figures ([0031] and [0032]) refers to entities DT1, DT2, and DT3 whereas Figures 2 and 3 contain entities labeled 1, 2, and 3..

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 3, 7-9, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramanian, et al. (WO 98/48048). The claims are drawn to a multi-component detection system comprising three fluorescently tagged groups capable of interacting with each other in the following way: Tag 1 is capable of exciting each of tag 2 and tag 3 *via* FRET; tag 2 is capable of exciting tag 3 *via* FRET; and an appropriate energy source. Further limitations of the claims include: The interacting groups include, inter alia, proteins and polynucleotides (claims 7-9); the fluorescent moiety includes “any molecule with fluorescent properties”; and “any emitting light source”. Balasubramanian, *et al.* teaches systems comprising FAM, TMR and ROX labeled nucleotide probes (see Figure 1) and fluorescent spectrometers (see page 4, line 22). It is well known that the fluorescence emission spectra of FAM overlaps with absorption spectra of both TMR and ROX; the fluorescence emission spectra of TMR overlaps with the absorption spectra of ROX; and that modern fluorescence spectrometers can be adjusted to excite all three fluorophores (see, for example, Marras, Table 3).

Unlike claims 20 and 22, claim 3 requires that the components exist, not that they are used in a sequential manner. Thus, Balasubramanian, *et al.* teaches all the limitations of claims 3, 7-9, 16, and 18 and the claims are properly rejected under 35 U.S.C. 102(b).

6. Claims 3, 7-9, 16, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu and Lu. The limitations of claims 3, 7-9, 16, and 18 are outlined above (see section 3.); claim 20 adds the following additional limitations: The first detection tag is activated then emission of all three tags are detected and the second detection tag is activated the emission of the second and third tags are detected. Liu and Lu uses FRET to study the structure and dynamics of triply labeled DNAzymes. Liu and Lu teaches a combination of fluorophores that allows FRET between the first and both of the other fluorophores as well as FRET between the second and third fluorophores. The Results section (see page 15212) specifically teaches exciting the first fluorophore (FAM) at 490 nm and obtaining emission spectra; emission peaks obtained at 518, 580 and 660 nm correspond to the combination of emissions from each of the fluorophores (FAM, TMR and Cy5). Similarly, excitation a 560 nm, revealed emission peaks at 580 and 660 nm corresponding to emission from TMR and Cy5 (see, especially, figure 2). Thus, each and every limitation of claims 3, 7-9, 16, 18 and 20 is taught by Liu and Lu and the claims are properly rejected under 35 U.S.C. 102(b).
7. Claims 3, 7-9, 16, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2004/029579 (Amersham Biosciences, Corp). The limitations

of the claims are described above. WO 2004/029579 teaches fluorescent labeling reagents with multiple donors and acceptors; the fluorophore interact as has been described above and evidenced by Figures 4 and 8. The fluorophores are intended for use with, *inter alia*, proteins and DNA molecules as evidenced by the target groups listed in Table 1 (page 9) and claim 28. Thus, WO 2004/029579 teaches all the limitations of claims 3, 7-9, 16, and 18 and the claims are properly rejected under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3, 7, 8-20 and 22-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3, and consequently all dependent claims, is indefinite in several aspects described below:

Claim 3 multiply recites the phrase "interacting group". A careful search of the Specification fails to inform a reader of any special meaning of the phrase. Miriam-Webster Online Dictionary defines the word "interact" to mean: to act upon one another; the word "group" is defined as: two or more figures forming a complete unit in a composition. The simplest system that satisfies the requirements of an "interacting group" would be a dense solution of three fluorophores with overlapping emission/absorption

spectra; the molecules comprising the solvent certainly would interact with each other and the fluorophores. Taking into account the examples of the Specification, such a solution was clearly not contemplated by Applicants but is not outside a reasonable interpretation of the claim. Furthermore, given the open-endedness of the Specification's language, repeatedly using phrases such as, "a system for detecting molecular associations", "other biologically relevant molecules", "the following non-limiting examples", and "not be taken in any way as a restriction on the generality of the invention", it is unclear what limitations the inventors contemplated by the language of the claim.

Claim 3 recites "first tag emits light" and later "second tag can accept the energy from the first tag". The latter phrase is broader than the first and would encompass, *inter alia*, kinetic energy as well as light energy emitted from the first tag.

Claim 3 recites "an appropriate substrate or energy source to activate the tags in i) and ii)". It is unclear whether the meaning is intended to be that the energy source activates the first and second tags simultaneously or is merely capable of activating each. Also, it is unclear whether the phrase encompasses a previously undisclosed substrate that is capable of activating the second tag.

Because of the several ambiguities of the claim described above, the metes and bounds of the claim are not ascertainable and claim 3 as well as all dependent

claims are indefinite. Thus, all claims are properly rejected under 35 U.S.C. 112, second paragraph.

Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner

Application/Control Number: 10/580,130
Art Unit: 1648

Page 8

Art Unit 1648

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